**Initial approval 9/2009**
**Most recent modification 11/2014**

**NDA 22-110 VIBATIV® (telavancin) for injection**
**[Lipoglycopeptide]**

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# RISK EVALUATION AND MITIGATION STRATEGY (REMS)

## I. GOALS

The goals of the VIBATIV REMS are:

A. To inform healthcare professionals (HCP) about the increased risk of mortality associated with VIBATIV in patients with pre-existing creatinine clearance of ≤50 mL/min being treated for hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP)

B. To avoid unintended exposure of pregnant women to VIBATIV through:
- Educating healthcare professionals and patients on the potential risk of fetal developmental toxicity if women are exposed to VIBATIV while pregnant
- Informing HCPs that a serum pregnancy test should be performed before initiating therapy with VIBATIV in Females of Reproductive Potential (FRP)
- Informing HCPs that FRP, including those being treated in the outpatient setting, should be counseled about pregnancy prevention and use of effective contraception during VIBATIV use

## II. REMS ELEMENTS

### A. Medication Guide

A Medication Guide will be dispensed with each VIBATIV prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

### B. Communication Plan

Theravance Biopharma Antibiotics, Inc. will implement the following elements of a communication plan:

1. **A Dear Healthcare Provider (DHCP) Letter** will be sent within 60 days, and again at 6 months, 1 and 2 years of approval, of the most recent REMS modification. The letter will be sent through either hardcopy mailings by U.S. mail or email to healthcare professionals likely to prescribe or dispense VIBATIV. This includes, but is not limited to healthcare professionals who practice in: hospitals, infectious disease,

emergency medicine, critical care, general surgery, obstetrics and gynecology, family practice and outpatient infusion centers. Subsequent letters will be sent to any new health care provider that was not initially sent the appended DHCP letter. The DHCP Letter will be distributed with the VIBATIV Package Insert and Medication Guide.

a. The letter will be available via a link from the VIBATIV website at www.vibativ.com and as well as from the medical information department for a period of one year after the approval of the most recent modification of the REMS. The letter will include Pregnancy Registry Information.

b. The Dear HCP Letter will be sent to the leadership of the following professional organizations with a request that these organizations disseminate the content of the letter to their professional membership:

Infectious Disease Society of America
American College of Emergency Physicians
Society of Critical Care Medicine
Society of Hospital Medicine
Surgical Infection Society
American Thoracic Society
American College of Chest Physicians
American College of Obstetrics and Gynecology
Outpatient Parenteral Antimicrobial Therapy
American Medical Association
American Hospital Association
Federation of American Hospitals
American Society of Health-System Pharmacists
American College of Clinical Pharmacists
Society of Infectious Disease Pharmacists
American College of Clinical Pharmacists
American Pharmacists Association
Premier

2. The email will target physicians based on the American Medical Association database. The email distribution list for other healthcare providers will be based on other databases and secured through a private contractor.
3. Providers that have an email address on file will receive the DHCP Letter via email. If the intended recipient does not open the DHCP Letter within 10 days, the materials will be distributed hardcopy via U.S. mail. The healthcare providers on the target audience list who do not have an email on file will receive a hardcopy via U.S. mail.
4. The DHCP letter will be provided to MedWatch at the same time it is provided to the professional organizations.

The DHCP Letter is part of the REMS and is appended.

C. **Timetable for Submission of Assessments**

Theravance Biopharma Antibiotics, Inc. will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years following the approval date of the most recent modification of the REMS (6/2013).

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Theravance Biopharma Antibiotics, Inc. will submit each assessment so that it will be received by FDA on or before the due date.